REMARKS

Status of the Claims

Claims 13, 15-55, 57, 59, and 60 are withdrawn. Claims 1 and 58 are amended. Claims 1-65 are in the case.

Rejections Under §112

A. The Action rejects claims 1-12, 14, 56, and 58 on the ground that the claimed method of diagnosing breast cancer does not provide a complete and specific diagnosis of breast cancer, and no other types of cancers. Applicant submits that such a requirement does not reflect the current state of diagnostic methods. The Action's position appears to be based on the untenable position that a diagnostic method has to be completely tissue specific in order to be useful, and that a physician should be able to make a definitive diagnosis of breast cancer based on a single, unequivocal test. To the contrary, a person of skill in the art, such as a physician, understands that diagnosis is not so limited, but can also be understood as a very early indicator of the presence of, or an increased probability of the presence of a neoplastic condition including breast cancer. Although Applicant submits that one of skill would understand the meaning of diagnosis to include this concept, to facilitate allowance without further delays, claim 1 is amended to indicate that the diagnosis is a detection of an increased probability of the presence of breast cancer in a subject. Applicants submit that this amendment is not narrowing, but is merely another way of stating the full scope of the original claim. This amendment, however, responds to the Examiner's comments and presents the claims in better form for consideration on appeal in accordance with 37 CFR §1.116(a)(2).

The amendment to claim 1 finds support in the Specification at least at [0034] that states that the upregulation or otherwise altered expression of CXCL9 or FLJ20174 in a biological

sample relative to a normal control indicates the presence of cancer, and at [0039], for example, that states that high expression levels of CXCL9 and FLJ20174 have been detected in breast cancer and ovarian cancer samples, while normal tissues show minimal or undetectable expression of CXCL9 or FLJ20174.

Thus the amendment to claim 1 is enabled and is fully supported by the Specification. Applicants respectfully request the Examiner to enter the amendment and to withdraw this ground of rejection.

B. The Action also rejects claims 1-8, 14, 56, 58 and 65 under 37 CFR §112 based on the ground that the definition of FLJ20174 is thought by the Examiner to encompass a broad range of unknown gene products. Applicants submit that the Action's position is purely theoretical and that no evidence has been presented that such a broad scope of gene products actually exists that would fall within the definition of FLJ20174. Absent any evidence to the contrary, and none has been presented, Applicants submit that one of skill in the art would clearly understand the scope of the claim term, FLJ20174, and could practice the claimed invention based on that understanding.

The Examiner is requested to present evidence or sound scientific reasoning that would provide some basis for the position that the FLJ20174 gene product encompasses a broad range of proteins or genes that actually exist and are expressed in a subject and that would effect the scope of the claim. The Action's position ignores the aspect of the claim that the claimed markers have to be expressed at detectable levels in the subject's tissue. Even if one can imagine a large number of variants, therefore, there is no such evidence that such variants are actually expressed in any tissue. Thus the claims are reasonable in scope and cover what is understood in the art to

be the genes or gene products identified by CXCL9 and FLJ20174. Absent any evidence to the contrary, Applicants request that this rejection be withdrawn.

C. The Action also rejects claims 1-9, 14, 56, 58, and 65 for lack of written description, apparently based on the same unsupported rejection as in (B.) above, that hypothetically there exist numerous genes or proteins that would wall within the claimed expressed products, and extending that erroneous rejection to include even hypothetical genes that do not even include the disclosed sequences.

Applicants submit that one of skill in the art would understand that detecting the expression in the sample of a nucleic acid comprising 30 or more contiguous nucleotides of SEQ ID NO:1, SEQ ID NO:3 or SEQ ID NO:4 would be sufficient to practice the invention of the rejected claims. There is no teaching in the Specification, and no expectation in the art that proteins with unrelated sequences exist, or that such proteins would fall within the definition of FLJ20174. The Examiner has not revealed even a single example of such a protein, that would fall within the scope of claim 1, and especially no protein or gene that would fall within the scope of claim 9.

Additionally, the Action does nothing to establish a *prima facie* case of alleged lack of written description. The Action applies an incorrect standard for making the rejection, and providing no analysis of what one of skill in the art would consider the inventor to have possessed at the time the application was filed. According to the MPEP, the Examiner is required to provide reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed.

The Federal Circuit has recently re-stated this requirement for the written description requirement:

A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. See *Union Oil Co. v. Atl. Richfield Co.*, 208 F.3d 989, 997 [54 USPQ2d 1227] (Fed. Cir. 2000). That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. *In re GPAC Inc.*, 57 F.3d 1573, 1579 [35 USPQ2d 1116] (Fed. Cir. 1995). Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation. *Lizard Tech, Inc. v. Earth Resource Mapping* 424 F3d 1336, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005)

Applicants submit that one of skill would have no trouble understanding that the Applicants possessed the claimed invention, diagnosing an increased probability of breast cancer by detecting upregulation of CXCL9 or FLJ20174. Such a person of skill would not engage in the kind of theoretical exercise as that presented in the Action to try to manufacture a rejection.

Furthermore, the rejection must fail because the Examiner has made no attempt to determine how one of skill would view the claims and has presented no evidence that such a person would adopt the Action's flawed interpretation of the claims. For these reasons, Applicants submit that the Specification contains sufficient written description to convey to **one of skill in the art** that the Applicants were in possession of the claimed invention at the time the Application was filed. Nothing more is required.

Applicants request therefore, that the written description rejection and all rejections under §112 be withdrawn.

CONCLUSION

Applicants believe that the claims are in condition for allowance. Such favorable action is respectfully requested. If the Examiner has any questions or comments regarding any issue associated with this application a telephone call to the undersigned representative at 512.542.8446 is welcome.

Respectfully submitted,

/Timothy S. Corder/
Registration. No. 38,414
Agent for Applicant

VINSON & ELKINS L.L.P.
First City Tower
1001 Fannin Street, Suite 2300
Houston, Texas 77002-6760
Ph: 512.542.8446

Date: September 10, 2007